

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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IN RE: NEW YORK DIET DRUG LITIGATION
-----X

Master Index No. 7000(1)/98

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

-----X
DORIS WELLER,

Plaintiff,

SUMMONS

-against-

Index No. 03..15476

AMERICAN HOME PRODUCTS CORP.;
A.H. ROBINS COMPANY INC.; WYETH
LABORATORIES, INC.; WYETH-AYERST
PHARMACEUTICALS, INC.; WYETH-AYERST
INTERNATIONAL, INC.; and WYETH,

Defendants.

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To the above named Defendants

You are hereby summoned to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the plaintiff's attorneys within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: Great River, New York
July 2, 2003

Yours, etc.

HARITON & DANVELO, LLP
Attorneys for Plaintiff

By 
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2003 JUL -8 AM 11:52
MARIO D. DANVELO
CLERK OF
SUFFOLK COUNTY

100-110

DEPENDANTS' ADDRESS:

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Madison, New Jersey 07940**

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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IN RE: NEW YORK DIET DRUG LITIGATION

Master Index No. 700000198

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

-----X
DORIS WELLER,

Plaintiff,

VERIFIED COMPLAINT

-against-

Index No.

AMERICAN HOME PRODUCTS CORP.;
A.H. ROBINS COMPANY, INC.; WYETH
LABORATORIES, INC.; WYETH-AYERST
PHARMACEUTICALS, INC.; WYETH-AYERST
INTERNATIONAL, INC; and WYETH,

Defendants.

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Plaintiff, DORIS WELLER, by her attorneys HARITON & D'ANGELO, LLP,
for her Verified Complaint against the above named defendants, upon information and
belief, allege:

**THE PURPORTED SETTLEMENT OF ALL DIET
DRUG PRODUCT LIABILITY LITIGATION UNDER
THE "NATIONAL CLASS ACTION SETTLEMENT
WITH AMERICAN HOME PRODUCTS, INC."**

1. This is a diet drug case arising from plaintiff DORIS WELLER's ingestion of fenfluramine, phentermine and/or dexfenfluramine ("Fen-Phen").
2. The allegations set forth in this section are not offered as affirmative claims or as a basis of jurisdiction, but in recognition of the fact that the defendants here will likely assert preclusion of these plaintiffs' claims on the basis of the NATIONAL CLASS ACTION SETTLEMENT WITH AMERICAN HOME PRODUCTS, INC., ("Settlement

Agreement"). That Settlement Agreement does not bind these plaintiffs, as their injuries did not manifest themselves until after the expiration of the deadline dates set forth in that agreement.

3. Most Fen-Phen related injuries are settled claims covered by the *Brown v. American Home Products-Diet Drug NATIONAL CLASS ACTION SETTLEMENT WITH AMERICAN HOME PRODUCTS, INC.* U.S. District Judge Louis Bechtel of the Eastern District of Pennsylvania approved the Settlement Agreement in that Court's Pretrial Order No. 1415.

4. Pretrial Order 1415 purports to bar prosecution of all covered claims by class members who have not met certain criteria, filed claim forms with supporting documents within certain deadlines or who have opted out of the Settlement Agreement by certain deadlines.

5. No provision was made in the Settlement Agreement nor in any pretrial order arising thereafter to compensate individuals whose injuries did not manifest themselves until after the Settlement Agreement's deadlines for compensation and/or opting out of the Settlement had elapsed.

6. No provision was made in the Settlement Agreement nor in any pretrial order for separate counsel to represent the interests of individuals whose injuries did not manifest themselves until after the Settlement deadlines for compensation and/or opting out of the Settlement had elapsed.

7. No provision was made in the Settlement Agreement nor in any pretrial order to create a subclass of class members diagnosed as "FDA positive", as that term is defined within the Settlement Agreement, on or after September 30, 1999, the deadline

for submitting claims forms to obtain compensation under the Agreement. Instead, class member whose interests were at odds were maintained in one class, in violation of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997) and *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999).

8. No separate counsel was provided to represent the interests of class members who would receive nothing under the terms of the Settlement because their diet drug injuries became evident or were diagnosed after the September 30, 1999 deadline for submitting claims. Instead, all class members, including those who were and were not entitled to benefits under the Agreement, were improperly represented by the same counsel, in violation of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997) and *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999).

9. Plaintiff DORIS WELLER is suffering from mild aortic regurgitation, as that condition is defined by the Settlement. She was first diagnosed with mild aortic regurgitation on or about June 11, 2003. Under the express provisions of the Settlement and subsequent orders entered by the federal court implementing the Settlement, cardiac-valvular injuries caused by the ingestion of diet drugs are not subject to compensation after May 3, 2003, the last date permitted for opting out of the Settlement and because the deadline has long since passed to submit claims under the Settlement. However, pursuant to *Amchem*, *Ortiz*, and *Stephenson v. Dow Chemical Co.*, 273 F.3d 249 (2d Cir. 2001) *aff'd per curiam*, 123 S. Ct. 2161 (2003), plaintiff, whose injuries did not manifest themselves until after the Settlement deadlines had expired, was not separately nor adequately represented in the class action. As such, plaintiffs' claims are not barred by the terms of the Settlement and she is entitled to prosecute this personal injury lawsuit.

THE PARTIES

10. Plaintiff DORIS WELLER is a residents and citizen of the State of New York, County of Suffolk. Plaintiff DORIS WELLER suffers from injuries resulting from the use of, fenfluramine, phentermine, and/or dexfenfluramine which were prescribed to her for combination use.

11. Defendant AMERICAN HOME PRODUCTS CORPORATION (hereinafter "Defendant") is a Delaware corporation whose principal place of business is or was in the State of New Jersey. Defendant is or was in the business, *inter alia*, of formulating, developing, manufacturing, marketing, distributing and selling, for profit, pharmaceutical products or drugs throughout the United States, including in and for the State of New York. Beginning with Pondimin in the 1960s and Redux in 1996, defendant, through itself and/or through subsidiaries, formulated, developed, manufactured, marketed, distributed and/or sold these two weight-loss and diet control drugs to several million consumers in the United States, including in and for the State of New York. On March 11, 2002, American Home Products Corporation changed its name to defendant WYETH.

12. Defendant A.H. ROBINS COMPANY, INC., (hereinafter "Robins" or, collectively, as "defendant"), is or was a Delaware corporation whose principal place of business is or was in Virginia, merged into AMERICAN HOME PRODUCTS CORPORATION on or about August 3, 1998, thereafter ceasing to exist as a separate entity. Accordingly, AMERICAN HOME PRODUCTS CORPORATION assumed all liability for all actions relevant hereto that had previously been undertaken by Robins.

Pondimin, a brand name for fenfluramine, had been manufactured, marketed, distributed and sold by defendant to several million consumers in the United States, including in and for the State of New York.

13. Defendant WYETH-AYERST PHARMACEUTICALS, INC., (hereinafter "Wyeth-Ayerst" or, collectively, as "defendant"), is or was a New York corporation whose principal place of business is or was in Pennsylvania, and is or was a subsidiary of AMERICAN HOME PRODUCTS CORPORATION. On January 1, 1999, defendant WYETH LABORATORIES, INC., a subsidiary of AMERICAN HOME PRODUCTS CORPORATION, with its principal place of business in Pennsylvania and its incorporation in New York, was merged into Ayerst Laboratories, Inc. The surviving entity was Ayerst Laboratories Inc., the name of which was changed to WYETH-AYERST PHARMACEUTICALS, INC. As its parent, AMERICAN HOME PRODUCTS CORPORATION assumed all liability for actions relevant hereto, for both WYETH LABORATORIES, INC. and WYETH-AYERST PHARMACEUTICALS, INC. At all times relevant, WYETH LABORATORIES, INC., formulated, developed, manufactured, marketed, distributed and/or sold the aforementioned drugs to several million consumers in the United States, including in and for the State of New York.

14. Defendant, WYETH-AYERST INTERNATIONAL, INC. is a New York corporation and is a subsidiary of WYETH. At all times relevant, WYETH-AYERST INTERNATIONAL, INC., distributed, promoted and/or sold the products manufactured by Wyeth and/or its subsidiaries, licensees and licensors, worldwide in markets other than the United States. WYETH-AYERST INTERNATIONAL, INC., was, at all relevant times, also in the business of promoting, marketing, manufacturing

and distributing the pharmaceuticals fenfluramine, dexfenfluramine and other drugs mentioned herein and formulated, developed, manufactured, marketed, distributed and/or sold the aforementioned drugs to several million consumers in the United States including the State of New York, and in countries outside the United States.

15. Defendant WYETH (hereinafter, "Wyeth" or, collectively, "defendant") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in the State of New Jersey. At all relevant times, WYETH was in the business of promoting, marketing, manufacturing and distributing the pharmaceuticals fenfluramine, dexfenfluramine and other drugs mentioned herein. At all times relevant, WYETH formulated, developed, manufactured, marketed, distributed and/or sold the aforementioned drugs to several million consumers in the United States, including in and for the State of New York. WYETH is the successor entity and assumes all liability for AMERICAN HOME PRODUCTS CORPORATION, A.H. ROBINS COMPANY, INC., WYETH-AYERST PHARMACEUTICALS, INC., and WYETH LABORATORIES, INC., in Fen-Phen diet drug litigation. Further, upon information and belief, defendant WYETH is the parent and/or successor entity for The Wyeth-Ayerst Laboratories Division of American Home Products Corporation. In light of all of the forgoing, any and all references to A.H. Robins, Wyeth-Ayerst Laboratories Division of American Home Products Corporation, Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth-Ayerst International, Inc., Wyeth Laboratories, Inc. or American Home Products Corporation ("AHP") are references to defendant WYETH, and all references to defendant WYETH are references to each of those previous entities.

16. At all times mentioned herein, WYETH-AYERST INTERNATIONAL, INC., and/or its overseas affiliates and/or licensees, pursuant to the protocol of WYETH and/or its predecessors, was to provide and provided WYETH with reports of foreign adverse drug events relevant to the drugs formulated, developed, manufactured, marketed, distributed and/or sold by WYETH and/or its licensees and/or licensors in foreign markets.

GENERAL ALLEGATIONS

17. At all relevant times WYETH, itself or by use of others, did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, advertise, and otherwise distribute in interstate commerce the diet drugs Pondimin (fenfluramine) and Redux (dexfenfluramine). Fenfluramine and/or dexfenfluramine, both alone and in combination with other medications, have been widely promoted by WYETH as effective and safe for weight loss.

18. Plaintiff DORIS WELLER is complaining of injuries as the result of the use of the weight loss medications fenfluramine and/or dexfenfluramine, which were ingested in or about June 1996 through July 1997, inclusive.

19. Fenfluramine was one of the drugs prescribed in combination with phentermine; they were promoted and referred to as "fen/phen." WYETH marketed fenfluramine under the trade name "Pondimin." In doing so, WYETH actively encouraged, and/or failed to effectively discourage, the combined use of fenfluramine with phentermine because it knew that the combined use would increase sales of fenfluramine.

20. Dexfenfluramine is the *d*-isomer of fenfluramine, containing the same active ingredient as fenfluramine. WYETH marketed dexfenfluramine under the trade name Redux.

21. Fenfluramine (Pondimin) and dexfenfluramine (Redux) were abruptly withdrawn from the market on September 15, 1997. Prior to that withdrawal, these drugs were sold to millions of people subjecting them to serious risk of bodily harm including pulmonary hypertension ("PH") or primary pulmonary hypertension ("PPH"), an often-fatal lung disease, and heart valve damage.

22. WYETH knew of the serious side effects of fenfluramine and/or dexfenfluramine for a substantial period of time. These side effects were known or should have been known to WYETH at the time that they marketed the drugs to the public based on, among other things, medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere, as detailed below. WYETH did not, however, conduct adequate testing to establish the safety of the drugs before marketing them. Rather, WYETH aggressively marketed the drugs and promoted their use, both individually and in combination with other drugs, while downplaying evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

23. WYETH's strategy, beginning in the early 1990s, was to aggressively market fenfluramine, often by encouraging its use in combination with phentermine, by falsely misleading potential users about fenfluramine and by failing to protect users from serious dangers that WYETH knew or should have known could result from use of fenfluramine.

24. WYETH widely and successfully marketed fenfluramine and/or dexfenfluramine in the United States.

25. WYETH undertook a promotional campaign that included the placement of numerous articles in scientific, medical and general interest magazines extolling the virtues of fenfluramine combined with phentermine in order to induce widespread use of the product. Many of these articles either cited or reported the results of studies that were funded by WYETH. Thus, WYETH actively encouraged, or failed to effectively discourage, combinations of these drugs.

26. Further, WYETH actively encouraged, or failed to effectively discourage, combinations of these drugs by employing and/or contracting with commission based salespersons to promote the widespread prescribing of fenfluramine and/or the combination of fenfluramine and phentermine to patients that were not clinically obese.

27. The marketing program as a whole, by affirmative misrepresentations and omissions, falsely and fraudulently sought to create the image and impression that the use of fenfluramine, both individually and/or in combination with phentermine, was safe for human use, had fewer side effects and adverse reactions than other methods of weight loss, constituted a convenient, safe form of weight loss and would not interfere with daily life.

28. WYETH purposefully downplayed and understated the health hazards and risks associated with fenfluramine and/or dexfenfluramine.

29. WYETH falsely and fraudulently concealed relevant information from doctors and potential fenfluramine and/or dexfenfluramine users regarding the safety of fenfluramine and/or dexfenfluramine.

30. In particular, WYETH's marketing efforts as well as their product inserts falsely, fraudulently and negligently misrepresented a number of facts regarding fenfluramine and/or dexfenfluramine including the following:

- a. The presence of adequate testing of fenfluramine and the presence of adequate testing of any combination use of the product with phentermine.
- b. Fenfluramine and/or dexfenfluramine's efficacy including but not limited to the severity, frequency and discomfort of side effects and adverse health effects caused by the drugs.
- c. The relative risks associated with the drugs including the prevalence of pulmonary hypertension, primary pulmonary hypertension and valvular heart disease.

31. In 1965, the diet drug "Aminorex" was introduced in Europe. Aminorex was touted as a wonder weight loss drug that worked by increasing brain serotonin and inhibiting reuptake of serotonin. However, by 1967 evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next six years, an Aminorex-related epidemic of primary pulmonary hypertension raged in Europe where a ten-fold increase in primary pulmonary hypertension cases was documented. Half of the patients died within ten years and the rest of the patients suffered significant oxygen deprivation and are debilitated for the remainder of their lives. Aminorex was removed from the European market in 1972. WYETH knew, or should have known, of the European experience with Aminorex and how it would relate to WYETH's drugs Pondimin and Redux three (3) decades later.

32. In 1973, Pondimin was introduced into the United States market. Pondimin is a fenfluramine drug, is in the same family of drugs as Aminorex and is very similar to Aminorex. Pondimin was touted as a wonder weight loss drug that worked by

increasing brain serotonin and inhibiting reuptake of serotonin. However, because the drug, when used alone, made users lethargic and tired, sales of Pondimin languished.

33. On October 3, 1981, Dr. J.G. Douglas published *Pulmonary Hypertension and Fenfluramine* in the BRITISH MEDICAL JOURNAL. On January 25, 1986 an article entitled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, was published in the BRITISH MEDICAL JOURNAL. WYETH knew, or should have known of the BRITISH MEDICAL JOURNAL articles and how those articles related to their drug Pondimin a decade later.

34. In 1984, Dr. Michael Weintraub published *A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination* in ARCHIVES OF INTERNAL MEDICINE. Dr. Weintraub's study was supported by A.H. Robins (which was later acquired by AHP). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub entirely failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually and in combination.

35. In 1992, Dr. Weintraub published a series of articles in CLINICAL PHARMACOLOGICAL THERAPIES, in which he reported his research regarding the long-term use of fenfluramine and phentermine for weight control. Dr. Weintraub's research was supported by WYETH.

36. Dr. Weintraub's research assumed the safety of fenfluramine and did not examine the short-term or long-term safety of the drug. Further, WYETH failed to conduct or fund any studies or research regarding the long-term safety of its fenfluramine drug, Pondimin. Nevertheless, WYETH did promote to physicians and the public Dr.

Weintraub's conclusion that long-term combination use of fenfluramine and phentermine was effective for the management of obesity.

37. By 1993, WYETH's labeling for Pondimin indicated that there were only four reported cases of pulmonary hypertension associated with the drug. Yet, that same year, Dr. François Brenot published *Primary Pulmonary Hypertension and Fenfluramine Use* in the BRITISH HEART JOURNAL. Dr. Brenot identified 25 cases of primary pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. WYETH knew or should have known of the Brenot article. WYETH should have known by at least 1993 that Pondimin was defective and unreasonably dangerous. WYETH should have known by at least 1993 that WYETH's labeling of Pondimin was false.

38. On June 24, 1994, WYETH Safety Surveillance Monitor, Arny Myette, wrote a memo to WYETH's Medical Monitor, Fred Wilson, and indicated that WYETH's database contained 37 cases of primary pulmonary hypertension associated with Pondimin. Further, in February 1994, the preliminary results of the International Primary Pulmonary Hypertension study ("IPPH Study"), entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension," were released and available to WYETH. The preliminary results of the IPPH Study confirmed the association between the drugs fenfluramine and dexfenfluramine, and the diseases of pulmonary hypertension and primary pulmonary hypertension. WYETH concealed the number of cases of primary pulmonary hypertension associated with Pondimin that WYETH knew existed in order to continue to market Pondimin for profit.

39. On June 15, 1995 AHP's James Ottinger reported to Joseph Barhish the status of the European Committee on Proprietary Medicinal Product's ("CPMP")

pharmacovigilance discussion wherein the CPMP working party concluded that a causal relationship between anorectic agents, like fenfluramine and/or dexfenfluramine, and the occurrence of primary pulmonary hypertension had been established.

40. The August 26, 1996 issue of the NEW ENGLAND JOURNAL OF MEDICINE reported the final results of the IPPH Study, which had been preliminarily released in February 1994. The IPPH Study concluded that fenfluramine-based anorexigens, such as fenfluramine and dexfenfluramine, increased the risk of PPH by a multiple of more than 23 times.

41. WYETH was aware of the result of the IPPH study by at least February 1994. Nevertheless, WYETH failed to apprise the public or physicians that the risk of contracting PH or PPH was many, many multiples of that previously reported by WYETH in their literature. Even after the Brenot article and the preliminary release of the IPPH Study, WYETH failed to remove Pondimin from the market when WYETH knew of the extreme danger, causal relationship and substantial risk of harm associated with the use WYETH's drug Pondimin.

42. WYETH continued to promote Pondimin after learning of the extreme danger associated with the drug. WYETH continued to promote Pondimin knowing the drug had no beneficial use. The WYETH labeling on the drug was totally inadequate to alert prescribing physicians and patients of the actual PH or PPH danger and risk associated with its fenfluramine drug, Pondimin. WYETH knew that danger and that risk.

43. Even after it knew of the danger, WYETH did not remove Pondimin from the market and did not do any further testing of the drug. Instead, WYETH continued to

market the drug to prescribing physicians like the physician that prescribed the diet drugs to the plaintiff in this case.

44. Further, in 1996 WYETH introduced its dexfenfluramine drug, Redux, into the United States market. This, despite the fact that WYETH knew of the danger and risks of valvular heart disease and primary pulmonary hypertension associated with Pondimin.

45. WYETH did not adequately or appropriately disclose the fenfluramine and/or dexfenfluramine information or related drug information to physicians in the United States. Instead WYETH fraudulently concealed the pulmonary hypertension or primary pulmonary hypertension danger about which it knew from physicians. As a result, physicians over-prescribed WYETH's fenfluramine and/or dexfenfluramine drugs, Pondimin and Redux, to patients who were grossly under-informed regarding the risk of PH or PPH associated with the drugs.

46. Although the FDA approved phentermine and fenfluramine separately, the FDA never approved the drugs for combined use. WYETH knew of and encouraged the prevalence of off-label combined use of its drugs, and failed to adequately and appropriately warn physicians and consumers that the combination drug regimen was not FDA approved, was hazardous due to the presence of fenfluramine, was not recommended and had not been systematically tested by appropriate clinical trials. Further, WYETH concealed, destroyed and removed written evidence and/or misrepresented evidence supporting the association between PH and/or PPH with fenfluramine and/or dexfenfluramine.

47. WYETH failed to fully and adequately warn doctors, the public and/or the Plaintiff about the risk of pulmonary hypertension from Pondimin and Redux.

48. In the early 1990s, WYETH received reports of valvular heart disease in patients taking fenfluramine and/or dexfenfluramine. However, WYETH failed to investigate the matter and failed to code their Adverse Drug Event reports appropriately so that valvular heart disease could be properly tracked and monitored. WYETH failed to conduct further testing of WYETH's drug Pondimin even after it knew of reports of valvular heart disease. WYETH continued to market its fenfluramine drug, Pondimin even after it knew of reports of valvular heart disease.

49. In 1997, a Safety Surveillance Monitor working for WYETH fraudulently destroyed, removed and concealed written Adverse Drug Event reports in WYETH's database files that demonstrated the association between fenfluramine and/or dexfenfluramine and valvular heart disease by "deleting" and "re-coding" them. The Safety Surveillance Monitor deleted and re-coded the reports at the direction of WYETH's senior management.

50. On or about July 8, 1997, the Mayo Clinic, located in Rochester, Minnesota, released an emergency report linking the use of fenfluramine to unusual, potentially life-threatening, valvular morphology and regurgitation in 24 women. The report observed that cardiovascular testing procedures, principally the echocardiogram procedure, revealed that each of the 24 patients had one or more heart valves that were thickened and that blood was regurgitating (or "leaking" backwards), making the heart work harder to pump blood throughout the body.

51. In addition, the Mayo Clinic report observed that eight of the patients had newly-documented pulmonary hypertension. Cardiac surgical intervention to replace bad valves was required in five of the twenty-four patients as of the date of the study.

52. The emergency release of the Mayo Clinic study, well in advance of its scheduled publication in the NEW ENGLAND JOURNAL OF MEDICINE, appears to have been motivated by the extraordinary incidence of life-threatening valvular heart disease and primary pulmonary hypertension experienced in persons who were taking fenfluramine.

53. The Mayo Clinic's study concludes that fenfluramine users needed to be informed about the risks of pulmonary hypertension and valvular heart disease, particularly because these conditions are extremely rare in individuals under 50 years old.

54. Subsequent research suggests that pulmonary hypertension and/or valvular heart disease may exist in a very significant portion of those who took fenfluramine and/or dexfenfluramine and that some of those suffering pulmonary hypertension and/or valvular dysfunction may be totally asymptomatic.

55. WYETH knew, or should have known about the risk of valvular heart disease associated with use of fenfluramine and/or dexfenfluramine. Yet WYETH failed to warn physicians and patients, including plaintiff, about the risk of valvular heart disease. Further, WYETH destroyed, removed and concealed written evidence and/or misrepresented evidence supporting the association between valvular heart disease and AHP's fenfluramine (Pondimin) and dexfenfluramine (Redux). The misrepresentations include, but are not limited to, the deletion, destruction, removal, concealment, mis-coding and re-coding of written Adverse Drug Event reports.

**AS AND FOR A FIRST CAUSE OF ACTION:
STRICT PRODUCT LIABILITY
(FAILURE TO WARN)**

56. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "55" as if fully set forth herein, and further allege as follows:

57. Defendants are manufacturers and/or suppliers of phentermine, fenfluramine and/or dexfenfluramine.

58. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants were and are unaccompanied by proper warnings regarding all possible adverse side effects associated with the use of phentermine, fenfluramine and/or dexfenfluramine and the comparative severity and duration of such adverse effects and the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

59. Defendants failed to perform adequate testing in that adequate testing would have shown that phentermine, fenfluramine and dexfenfluramine, used individually and/or in any combination thereof, possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made, both with respect to the use of any of these drugs individually and with respect to any combination use of these drugs.

60. Defendants also failed to effectively warn physicians and the public that other, more conservative methods of weight loss, including non-drug modalities such as diet control and exercise, should have been the first-used or even the only method of weight reduction physicians should prescribe for their patients who sought assistance

with weight reduction. This was particularly true in the case of patients who were not clinically obese or who, for any number of reasons, were high-risk patients.

61. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective due to inadequate post-marketing warning or instruction because, after the manufacturer knew or should have known of the risk of injury from phentermine, fenfluramine, dexfenfluramine and/or combination use of these drugs, it failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote the product.

62. As the producing cause and legal result of the defective condition of phentermine, fenfluramine and/or dexfenfluramine as manufactured and/or supplied by defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing, actions and/or omissions of defendants described herein: (a) Plaintiff has been injured in health, strength and activity and suffered injuries to body and mind, the exact nature and extent of which are not known at this time; (b) Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown; (c) Plaintiff required reasonable and necessary health care, attention and services and did incur medical, health incidental and related expenses. Plaintiff is informed and believes and thereon alleges that she may in the future be required to obtain medical and/or hospital care, attention and services in an amount as yet unascertained.

**AS AND FOR A SECOND CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY**

63. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "62" and incorporate same by reference as if fully set forth herein, and further allege as follows:

64. Defendants are manufacturers and/or suppliers of phentermine, fenfluramine and/or dexfenfluramine.

65. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

66. Alternatively, the phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of weight loss.

67. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective due to inadequate warning or instruction because the manufacturer knew or should have known that the product created a risk of harm to consumers and the defendants failed to adequately warn of said risks.

68. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective due to inadequate warning and/or inadequate testing.

69. The phentermine, fenfluramine and/or dexfenfluramine manufactured and/or supplied by defendants was defective due to inadequate post-marketing warning or instruction because, after the manufacturer knew or should have known of the risk of injury from phentermine, fenfluramine, dexfenfluramine and/or combination use of these drugs, it failed to provide adequate warnings to users or consumers of the product and continued to promote the product. The defendant (a) Failed to use due care in designing and manufacturing phentermine, fenfluramine and/or dexfenfluramine so as to avoid the aforementioned risks to individuals when phentermine, fenfluramine and/or dexfenfluramine were being used for weight loss; (b) Failed to accompany their product with proper warning regarding all possible adverse side effects associated with the use of phentermine, fenfluramine and/or dexfenfluramine and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects; (c) Failed to conduct adequate pre-clinical and clinical testing and post marketing surveillance to determine the safety of phentermine, fenfluramine and/or dexfenfluramine; (d) Failed to test for adverse effects on pregnancy and failed to warn women of the possible danger to the fetus if pregnancy occurs while phentermine, fenfluramine and/or dexfenfluramine is in use; (e) Failed to provide adequate training to medical care providers for appropriate use of phentermine, fenfluramine and/or dexfenfluramine either individually or in combination; (f) Failed to warn Plaintiff, prior to actively encouraging the sale of phentermine, fenfluramine, dexfenfluramine and/or any combination of these drugs, either directly or indirectly, orally or in writing, about the following; (1) the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal pulmonary and cardiac side

effects; (2) the possibility of becoming disabled as a result of valvular heart defects; (3) that such surgery may leave an unsightly scar or scars; or (4) that heart procedures, heart defects and/or primary pulmonary hypertension may become protracted, debilitating, difficult and painful, necessitating lengthy surgery and/or several visits to the doctors, clinic or hospital; and (g) Failed to adequately test and/or warn about the reaction or interaction of one or more of the component parts in phentermine, fenfluramine and/or dexfenfluramine.

70. As the producing cause and legal result of the defective condition of phentermine, fenfluramine and/or dexfenfluramine as manufactured and/or supplied by defendants and as a direct and legal result of the negligence, carelessness, other wrongdoing and actions of defendants described herein; (a) Plaintiff has been injured in health, strength and activity and suffered injuries to the body and mind; (b) Plaintiff has sustained economic loss, including loss of earnings and diminution or loss of earning capacity, the exact amount of which is presently unknown; (c) Plaintiff required reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and thereon alleges that plaintiff may in the future be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

**AS AND FOR A THIRD CAUSE OF ACTION:
NEGLIGENCE**

71. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "70" and incorporate same as if fully set forth herein and further allege as follows:

72. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of phentermine, fenfluramine and/or dexfenfluramine into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control and/or distribution of phentermine, fenfluramine and/or dexfenfluramine into interstate commerce in that defendants knew or should have known that the product phentermine, fenfluramine and/or dexfenfluramine created a high risk of unreasonable, dangerous side effects some of which, e.g., advanced valvular heart defects, can only be alleviated by open heart surgery or other invasive procedures and some of which, e.g., primary pulmonary hypertension, can be fatal.

73. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of phentermine, fenfluramine and/or dexfenfluramine, in that they: (a) Failed to use due care in designing and manufacturing phentermine, fenfluramine and/or dexfenfluramine so as to avoid the aforementioned risks to individuals when phentermine, fenfluramine and/or dexfenfluramine were being used for weight loss; (b) Failed to accompany their product with proper warnings regarding all possible adverse side effects associated with the use of phentermine, fenfluramine and/or dexfenfluramine and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects; (c) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of phentermine, fenfluramine and/or dexfenfluramine; (d) Failed to test for adverse effects on pregnancy and failed to warn

women of the possible danger to the fetus if pregnancy occurs while phentermine, fenfluramine and/or dexfenfluramine is in use; (e) Failed to provide adequate training to medical care providers for appropriate use of phentermine, fenfluramine and/or dexfenfluramine either individually or in combination; (f) Failed to warn Plaintiffs, prior to actively encouraging the sale of phentermine, fenfluramine, dexfenfluramine and/or any combination of these drugs, either directly or indirectly, orally or in writing, about the following: (1) the need for comprehensive regular medical monitoring to ensure early discovery of potentially fatal pulmonary and cardiac side effects; (2) the possibility of becoming disabled as a result of the drug use and/or having to undergo heart surgery in order to correct resultant valvular heart defects; (3) that such surgery may leave an unsightly scar or scars; or (4) that heart procedures, heart defects and/or primary pulmonary hypertension may become protracted, debilitating, difficult, and painful necessitating lengthy surgery and/or several visits to the doctor, clinic or hospital; (g) Failed to adequately test and/or warn about the reaction or interaction of one or more of the component parts in phentermine, fenfluramine and/or dexfenfluramine, including, without limitation, the possible adverse side effects caused by the reaction or interaction between the drugs as a result of combination use; (h) Failed to warn that brain serotonin levels are affected by the drug use which can cause other serious health risks and/or neurotoxicity; and (i) Failed to warn that the costs associated with phentermine, fenfluramine and/or dexfenfluramine could exceed other comparable forms of weight loss, particularly for those who were not clinically obese.

74. Likewise, WYETH was negligent and failed to exercise any care or acted intentionally or with malice in ever seeking approval for the sale of dexfenfluramine, given WYETH's knowledge of the dangers associated with fenfluramine.

75. WYETH was negligent in violating 21 U.S.C. §§ 321, 331, 352 and 355. Further, WYETH was negligent in violating 21 C.F.R. §§ 1.21, 99.101, 201.56, 201.57, 202.1, 310.303, 314.70, 314.80 and 314.81.

76. Despite the fact that defendants knew or should have known that phentermine, fenfluramine, dexfenfluramine and/or combination thereof caused unreasonable, incurable, progressive and dangerous side effects which many users would be unable to remedy by any means, defendants continued to market phentermine, fenfluramine, dexfenfluramine and combination use thereof to consumers including plaintiff, when there were safer alternative methods of weight loss.

77. Defendants knew or should have known that consumers such as plaintiff would suffer injury as a result of defendant's failure to exercise ordinary care as described above.

78. Defendants' negligence was a proximate cause of plaintiff's injuries, harm and economic loss which she suffered and will continue to suffer, as previously described.

**AS AND FOR A FOURTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY**

79. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs numbered "1" through "78" and incorporate same by reference as if fully set forth herein and further allege as follows:

80. Defendants expressly warranted that phentermine, fenfluramine and/or dexfenfluramine were safe and well accepted by patients studied.

81. Phentermine, fenfluramine and/or dexfenfluramine do not conform to these express representation because phentermine, fenfluramine and/or dexfenfluramine are not safe and have high levels of serious side effects, including life threatening side effects.

82. As a direct and proximate consequence of the breach of said warranties, plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein.

**AS AND FOR A FIFTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY**

83. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "82" and incorporate same by reference as if fully set forth herein and further allege as follows:

84. At the time defendants marketed, sold and distributed phentermine, fenfluramine and dexfenfluramine, defendants intended and impliedly warranted the products to be of merchantable quality and safe and fit for such use.

85. Plaintiff DORIS WELLER and her physicians reasonably relied upon the skill and judgment of defendants as to whether phentermine, fenfluramine, dexfenfluramine and combination use thereof were of merchantable quality and safe and fit for their intended use.

86. Contrary to such implied warranty, phentermine, fenfluramine, dexfenfluramine and combinations thereof were not of merchantable quality or safe or fit.

for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purpose for which they were used as described above.

87. As a direct and proximate result of the breach of the implied warranty, plaintiff suffered and will continue to suffer injury, harm and economic loss as alleged herein.

AS AND FOR A SIXTH CAUSE OF ACTION: FRAUD

88. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "87" and incorporate same by reference as if fully set forth herein, and further allege as follows:

89. At all relevant times, WYETH actually knew of the defective nature of Pondimin and/or Redux and continued to design, manufacture, market and sell the products so as to maximize sales and profits at the expense of the public's and plaintiff's health and safety in conscious and malicious disregard of the foreseeable harm caused by the drugs. WYETH acted intentionally and maliciously. WYETH, by its conduct, exhibited such a want of care as to establish that its actions were a result of fraud, malice, ill will, recklessness or willful and intentional disregard of the plaintiff's rights.

Therefore, plaintiffs are entitled to exemplary damages.

**AS AND FOR A SEVENTH CAUSE OF ACTION:
MISREPRESENTATION – FRAUD**

90. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs "1" through "89" and incorporate same by reference as if fully set forth herein, and further allege as follows:

91. WYETH, through advertising, labeling and other communications, made fraudulent, negligent or innocent misrepresentations of material fact concerning the product to physicians and/or the public, about the safety and efficacy of the Pondimin and Redux drugs for weight loss. Physicians justifiably relied on WYETH's misrepresentations and plaintiff was harmed as a result. Plaintiffs are entitled to recover damages for the injuries occasioned by WYETH's misrepresentations.

92. Pleading in the alternative, WYETH, through advertising, labeling and other communications, made misrepresentations to physicians and/or the public about the safety and efficacy of the Pondimin and Redux drugs for weight loss. Physicians justifiably relied on WYETH's misrepresentations and plaintiff was harmed as a result. Plaintiffs are entitled to recover damages for the injuries occasioned by WYETH's misrepresentations.

93. Further, WYETH, through advertising, labeling and other communications, intentionally made misrepresentations to physicians about the safety and efficacy of the Pondimin and Redux drugs for weight loss. From at least 1991 until 1997, WYETH's labeling for Pondimin stated that there had been only 4 cases of PH associated with the use of fenfluramine and/or dexfenfluramine. WYETH knew that the number was false and misleading and did nothing to correct the number so as to intentionally mislead physicians, to the detriment of their patients, including the plaintiff. WYETH also purposely failed to warn and failed to report to the FDA the incidence of PH and valvular heart disease associated with Pondimin and Redux use. At the trial of this case, Plaintiff will offer extensive testimony and numerous documents that evidence the fraud committed by WYETH with regard to the Pondimin labeling for PH.

94. Further, WYETH intentionally and knowingly engaged in a cover-up and fraudulently destroyed, removed and concealed written documents from the FDA and physicians in an illegal attempt to hide WYETH's knowledge of the association between valvular heart disease and Pondimin and Redux. WYETH's attempt to hide its knowledge was accomplished by the deletion, destruction, miscoding and re-coding of Adverse Drug Event reports. Safety Surveillance Monitor Amy Myers testified that in 1997 she deleted, destroyed, miscoded and/or re-coded Adverse Drug Event reports that evidenced the association between valvular heart disease and use of fenfluramine and dexfenfluramine. Ms. Myers' misconduct was authorized and approved by WYETH's senior management. Physicians relied on WYETH's fraudulent misrepresentations and the plaintiff was harmed as a result.

95. WYETH acted and made these misrepresentations with the intention and specific desire that the plaintiff and others similarly situated would rely upon them in choosing the diet drugs prescribed to, sold to and ingested by the plaintiff.

96. Plaintiff relied on and was induced by the acts and misrepresentations of WYETH in ingesting the diet drugs and plaintiff's use of the diet drugs directly and proximately caused all of her damages, as stated herein.

97. Plaintiffs are entitled to recover actual damages for their injuries as a result of WYETH's misrepresentations and fraud. Further, because WYETH's conduct was willful, reckless, intentionally and maliciously fraudulent, plaintiffs are entitled to an award of exemplary damages.

- THIRD CAUSE OF ACTION:** (NEGLIGENCE)
- FOURTH CAUSE OF ACTION:** (BREACH OF EXPRESS WARRANTY)
- FIFTH CAUSE OF ACTION:** (BREACH OF IMPLIED WARRANTY)
- SIXTH CAUSE OF ACTION:** (INTENTIONAL AND MALICIOUS CONDUCT - FRAUD)
- SEVENTH CAUSE OF ACTION:** (MISREPRESENTATION-FRAUD)
- EIGHTH CAUSE OF ACTION :** (VIOLATION OF GENERAL BUSINESS LAW §§ 349 AND 350)

including punitive and exemplary damages for each plaintiff; attorneys' fees, expenses and costs of this action and such further relief as this Court deems necessary, just and proper.

Dated: Great River, New York
July 2, 2003

Yours, etc.,

**HARITON & D'ANGELO, LLP
ATTORNEYS FOR PLAINTIFF**

By:

MARIO D'ANGELO

3500 Sunrise Hwy., Suite T-307
Great River, New York 11739
(631) 224-1133

**State of Service by Mail and
Acknowledgment of Receipt by Mail of
Summons and Complaint or Summons and Notice
or Notice of Petition and Petition**

DORIS WELLER

-against-

AMERICAN HOME PRODUCTS CORP., A.H. ROBINS COMPANY, INC., WYETH
LABS, INC., WYETH LABORATORIES, INC., WYETH-AYERST
PHARMACEUTICALS INC., WYETH-AYERST INTERNATIONAL, INC., and WYETH

**STATEMENT OF SERVICE
BY MAIL**

TO: American Home Products Corp.,
A.H. Robins Company, Inc.
WYETH LABORATORIES, INC.,
WYETH-AYERST PHARMACEUTICALS, INC.,
WYETH-AYERST INTERNATIONAL, INC.,
WYETH
Julia Feliciano, Esq.
Legal Division, 170-1
P.O. Box 8299
Philadelphia, PA. 19101

The enclosed summons and complaint or summons and notice, or notice of petition and petition are served pursuant to section 312 (a) of the Civil Practice Law and Rules.

To avoid being charged with the expense of service upon you, you must sign, date and complete the acknowledgment part of this form and mail or deliver one copy of the completed form to the sender within thirty (30) days from the date you receive it . If you wish to consult an attorney, you should do so as soon as possible before the thirty (30) days expire.

If you do not complete and return the form to the sender within thirty (30) days, you (or the party on whose behalf you are being served) may be required to pay expenses incurred in serving the summons and complaint, or summons and notice, or notice of petition and petition in any other manner permitted by law, and the cost of such service as permitted by law may be entered as a judgment against you.

If you have received a complaint of petition with this statement the return of this statement and acknowledgment does no relieve you of the necessity to answer the complaint or petition. The time to answer expires twenty (20) days after the date you mail or deliver this form to the sender. If you wish to consult with an attorney, you should do so as soon as possible before the twenty (20) days expire.

If you are served on behalf of a corporation, unincorporated association, partnership or other entity you must indicate under your signature your relationship to the entity. If you are served on behalf of another person and you are authorized to receive process, you must indicate under your signature your authority.

It is a crime to forge a signature or to make a false entry on this statement or on the acknowledgment.

Signature

Print name

Address

**ACKNOWLEDGMENT OF RECEIPT OF SUMMONS AND COMPLAINT OR
SUMMON AND NOTICE OR NOTICE OF PETITION AND PETITION**

I received a and complaint, or summons and notice, or notice of petition and petition in the above-captioned matter at (insert address) . PLEASE CHECK ONE OF THE FOLLOWING;

IF 2 IS CHECKED, COMPLETE AS INDICATED:

1. // I am not in the military service.
2. // I am in military service, and my rank, serial number and branch of service are as follows:

Rank

Serial number

Branch of Service

Date:

DATED: July 8, 2003

I affirm the above as true under penalty of perjury.

Signature

Print name

Relationship to entity/ Authority to Receive